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10/598,686	09/08/2006	Michael Gregory Bell	X-17098	8979
25885 7590 08/10/2009 ELI LILLY & COMPANY PATENT DIVISION			EXAMINER	
			COLEMAN, BRENDA LIBBY	
P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			ART UNIT	PAPER NUMBER
			1624	
			NOTIFICATION DATE	DELIVERY MODE
			08/10/2009	ELECTRONIC .

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail  $\,$  address(es):

patents@lilly.com

## Application No. Applicant(s) 10/598,686 BELL ET AL. Office Action Summary Examiner Art Unit Brenda L. Coleman 1624 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status Responsive to communication(s) filed on 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-14.17.21 and 24-30 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) \_\_\_\_\_ is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-14.17.21 and 24-30 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

| Attachment(s) | Attachment(s

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## DETAILED ACTION

Claims 1-14, 17, 21 and 24-30 are pending in the application.

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which

are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to

elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 5, 6, 8-14, 17, 21 and 24-29, drawn to the compounds, compositions and method of use of the compounds of formula I where W-X-Y-Z and j form a thieno[3,4-b]azepine ring.

Group II, claim(s) 1-3, 5, 6, 8-14, 17, 21 and 24-29, drawn to the compounds, compositions and method of use of the compounds of formula I where W-X-Y-Z and j form a thieno[3,2-b]azepine ring.

Group III, claim(s) 1-3, 5-7, 9-14, 17, 21 and 24-29, drawn to the compounds, compositions and method of use of the compounds of formula I where W-X-Y-Z and j form a pyrido[2,3-b]azepine ring.

Group IV, claim(s) 1-3, 5-7, 9-14, 17, 21 and 24-29, drawn to the compounds, compositions and method of use of the compounds of formula I where W-X-Y-Z and j form a pyrido[3,4-b]azepine ring.

Group V, claim(s) 1-3, 5-7, 9-14, 17, 21 and 24-29, drawn to the compounds, compositions and method of use of the compounds of formula I where W-X-Y-Z and j form a pyrido[4,3-b]azepine ring.

Group VI, claim(s) 1-3, 5-7, 9-14, 17, 21 and 24-29, drawn to the compounds, compositions and method of use of the compounds of formula I where W-X-Y-Z and j form a pyrido(3,2-b]azepine ring.

Group VII, claim(s) 1-3, 5, 6, 9-14, 17, 21 and 24-29, drawn to the compounds, compositions and method of use of the compounds of formula I where W-X-Y-Z and j form a pvrazoloi3.4-blazepine ring.

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Group VIII, claim(s) 1-13, 17, 21 and 24-29, drawn to the compounds, compositions and method of use of the compounds of formula I where W-X-Y-Z and j form a ring other than those embraced by Groups I-VII above.

Group IX, claim(s) 30, drawn to the complex compositions which include an additional active ingredient.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I-VII are directed to structurally dissimilar compounds such that the variable core created by the varying definitions of j, W, X, Y and Z in formula I do not belong to a recognized class of chemical compounds in the art, and references anticipating one invention, would not render obvious the others, for example thieno[3,4-b]azepine is different from thieno[3,2-b]azepine, pyrido[3,4-b]azepine, etc. Thus, separate searches in the literature as well as in the U.S. Patent Classification System would be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structures as functional equivalents of each other. The mere fact that there is a single similarity is not in itself a significant reason to render the whole embodiment obvious.

Groups I-VII and IX are directed to compounds of formula I and complex composition, which includes the compounds of Groups I-VII and an additional active ingredient.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record Application/Control Number: 10/598,686

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showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Tentative election of a single species within the elected group is further required.

If Groups VIII or IX are elected further restriction may be required.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/ Primary Examiner, Art Unit 1624